

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of claims:

1.-12. (Canceled)

13. (Previously presented) A method of treating asthma in a patient, the method comprising administering an effective amount of a composition comprising, in admixture:

(a) a first active ingredient that is formoterol, a pharmaceutically acceptable salt or solvate thereof or a solvate of such a salt; and

(b) a second active ingredient that is budesonide;
characterized in that the patient is administered (i) a maintenance dose of the composition twice per day, on a regular basis, and (ii) one or more additional doses on an irregular basis, wherein the one or more additional doses are administered as-needed, as determined by the patient.

14. (Previously presented) The method according to claim 13, wherein the molar ratio of (a) to (b) calculated as formoterol to budesonide is from 1:1 to 1:100.

15. (Previously presented) The method according to claim 13, wherein the first active ingredient is formoterol fumarate dihydrate.

16. (Previously presented) The method according to claim 13, wherein the first active ingredient is the R,R enantiomer of formoterol or a pharmaceutically acceptable salt or solvate of said enantiomer or a solvate of such a salt.

17. (Previously presented) The method according to claim 15, wherein the composition is in the form of unit doses, each of which delivers 1 µg to 48 µg of the first active ingredient, calculated as formoterol fumarate dihydrate.

18. (Previously presented) The method according to claim 15, wherein the patient is administered an amount per day of the composition, including for maintenance therapy, that contains a total of 1 µg to 100 µg of the first active ingredient, calculated as formoterol fumarate dihydrate.

19. (Previously presented) The method according to claim 13, wherein the second active ingredient is the 22R epimer of budesonide.

20. (Previously presented) The method according to claim 13, wherein the composition is in the form of unit doses, each of which delivers 20 µg to 1600 µg of budesonide to the patient.

21. (Previously presented) The method according to claim 13, wherein the patient is administered an amount per day of the composition, including for maintenance therapy, that contains a total of 20 µg to 4800 µg of budesonide.

22. (Previously presented) The method according to claim 13, wherein the particle size of the active ingredients (a) and (b) is less than 10 µm.

23. (Previously presented) The method according to claim 13, wherein the composition additionally comprises one or more pharmaceutically acceptable additives, diluents or carriers.

24. (Previously presented) The method according to claim 13, wherein the composition additionally comprises lactose monohydrate.

25. (Previously presented) The method according to claim 14, wherein the molar ratio of (a) to (b) calculated as formoterol to budesonide is from 1:1 to 1:70.

26. (Previously presented) The method according to claim 17, wherein the composition is in the form of unit doses, each of which delivers 3 µg to 12 µg of the first active ingredient to the patient, calculated as formoterol fumarate dihydrate.

27. (Previously presented) The method according to claim 18, wherein the patient is administered an amount per day of the composition, including maintenance therapy, that contains a total of 2 μg to 60 μg of the first active ingredient, calculated as formoterol fumarate dihydrate.

28. (Previously presented) The method according to claim 20, wherein the composition is in the form of unit doses, each of which delivers 50 μg to 400 μg of budesonide to the patient.

29. (Previously presented) The method according to claim 21, wherein the patient is administered an amount per day of the composition, including maintenance therapy, that contains a total of 30 μg to 3200 μg of budesonide.

30-33. (Canceled)

34. (Previously presented) The method of claim 36 wherein the asthma inducing condition is selected from the group consisting of exercise, exposure to cold air, exposure to pollen, exposure to perfume, and exposure to a smoky environment.

35. (Canceled)

36. (Previously presented) A method of treating asthma in a patient, the method comprising

administering an effective amount of a composition comprising, in admixture:

(a) a first active ingredient that is formoterol, a pharmaceutically acceptable salt or solvate thereof or a solvate of such a salt; and

(b) a second active ingredient that is budesonide;

characterized in that the patient is administered (i) a maintenance dose of the composition twice per day on a regular basis, and (ii) one or more additional doses on an irregular basis, wherein the one or more additional doses are administered when the patient expects to encounter an asthma inducing condition.

37-41. (Canceled)

42. (Previously presented) A method of treating asthma in a patient, the method comprising

administering an effective amount of a composition comprising, in admixture:

(a) a first active ingredient that is formoterol, a pharmaceutically acceptable salt or solvate thereof or a solvate of such a salt; and

(b) a second active ingredient that is budesonide;

characterized in that the patient is administered (i) a maintenance dose of the composition twice per day on a regular basis, and (ii) one or more additional doses, wherein the one or more additional doses are administered when the patient experiences an acute asthma attack.

43. (Previously presented) The method of claim 13, wherein the first and second active ingredients are both in dry powder form.

44. (Previously presented) The method of claim 13, wherein the composition is administered from a pressurized metered dose inhaler.

45. (Previously presented) The method of claim 44, wherein the first and second active ingredients are suspended in a liquid propellant.

46. (Previously presented) The method of claim 45, wherein the liquid propellant is one or more of P134a, P152a, and P227.

47. (Previously presented) The method of claim 45, wherein the liquid propellant is P227.

48. (Previously presented) The method of claim 13, wherein the composition is administered by the patient.

49. (Previously presented) A method of treating asthma in a patient, the method comprising administering an effective amount of a composition comprising, in admixture:

(a) a first active ingredient that is formoterol, a pharmaceutically acceptable salt or solvate thereof or a solvate of such a salt; and

(b) a second active ingredient that is budesonide;

characterized in that the patient is administered (i) a maintenance dose of the composition twice per day on a regular basis, and (ii) one or more additional doses on an irregular basis, wherein the one or more additional doses are administered when needed for symptom relief.

50. (Previously presented) A method of treating asthma in a patient, the method comprising administering an effective amount of a composition comprising, in admixture:

(a) a first active ingredient that is formoterol, a pharmaceutically acceptable salt or solvate thereof or a solvate of such a salt; and

(b) a second active ingredient that is budesonide;

characterized in that the patient is administered (i) a maintenance dose of the composition on a regular basis as determined by the patient's physician, and (ii) one or more additional doses on an irregular basis, wherein the one or more additional doses are administered when the patient determines the additional dose or doses are needed for symptom relief or when the patient expects to encounter an asthma inducing condition.

51. (Currently amended) A method of treating asthma in a patient, the method comprising administering one or more doses ~~of an effective amount~~ of a composition comprising, in admixture:

(a) a first active ingredient that is formoterol, a pharmaceutically acceptable salt or solvate thereof or a solvate of such a salt; and

(b) a second active ingredient that is budesonide;

characterized in that the patient is administered the one or more doses of the composition on an irregular basis when the patient determines the one or more doses are needed for symptom relief or when the patient expects to encounter an asthma inducing condition.

52. (Previously presented) The method of claim 36, wherein the first active ingredient is formoterol fumarate dihydrate.

53. (Previously presented) The method of claim 42, wherein the first active ingredient is formoterol fumarate dihydrate.

54. (Previously presented) The method of claim 49, wherein the first active ingredient is formoterol fumarate dihydrate.

55. (Previously presented) The method of claim 50, wherein the first active ingredient is formoterol fumarate dihydrate.

56. (Previously presented) The method of claim 51, wherein the first active ingredient is formoterol fumarate dihydrate.

57. (New) The method of claim 13, wherein the composition is inhaled by the patient from an inhaler, and each puff from the inhaler delivers 4.5 µg formoterol fumarate dihydrate and 80 µg budesonide to the patient.

58. (New) The method of claim 13, wherein the composition is inhaled by the patient from an inhaler, and each puff from the inhaler delivers 4.5 µg formoterol fumarate dihydrate and 160 µg budesonide to the patient.

59. (New) The method of claim 36, wherein the composition is inhaled by the patient from an inhaler, and each puff from the inhaler delivers 4.5 µg formoterol fumarate dihydrate and 80 µg budesonide to the patient.

60. (New) The method of claim 36, wherein the composition is inhaled by the patient from an inhaler, and each puff from the inhaler delivers 4.5 µg formoterol fumarate dihydrate and 160 µg budesonide to the patient.

61. (New) The method of claim 42, wherein the composition is inhaled by the patient from an inhaler, and each puff from the inhaler delivers 4.5 µg formoterol fumarate dihydrate and 80 µg budesonide to the patient.

62. (New) The method of claim 42, wherein the composition is inhaled by the patient from an inhaler, and each puff from the inhaler delivers 4.5 µg formoterol fumarate dihydrate and 160 µg budesonide to the patient.

63. (New) The method of claim 49, wherein the composition is inhaled by the patient from an inhaler, and each puff from the inhaler delivers 4.5 µg formoterol fumarate dihydrate and 80 µg budesonide to the patient.

64. (New) The method of claim 49, wherein the composition is inhaled by the patient from an inhaler, and each puff from the inhaler delivers 4.5 µg formoterol fumarate dihydrate and 160 µg budesonide to the patient.

65. (New) The method of claim 50, wherein the composition is inhaled by the patient from an inhaler, and each puff from the inhaler delivers 4.5 µg formoterol fumarate dihydrate and 80 µg budesonide to the patient.

66. (New) The method of claim 50, wherein the composition is inhaled by the patient from an inhaler, and each puff from the inhaler delivers 4.5 µg formoterol fumarate dihydrate and 160 µg budesonide to the patient.

67. (New) The method of claim 51, wherein the composition is inhaled by the patient from an inhaler, and each puff from the inhaler delivers 4.5 µg formoterol fumarate dihydrate and 80 µg budesonide to the patient.

68. (New) The method of claim 51, wherein the composition is inhaled by the patient from an inhaler, and each puff from the inhaler delivers 4.5 µg formoterol fumarate dihydrate and 160 µg budesonide to the patient.